UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Subcategory No. 06-11337 Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation Schering-Plough Corporation and Warrick Pharmaceuticals Corporation,* Civil Action No. 09-CV-10547; and *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation,* Civil Action No. 00-10698	

UNITED STATES' OBJECTION TO THE PROPOSED SETLEMENT BETWEEN SCHERING-PLOUGH CORPORATION, SCHERING CORPORATION, WARRICK PHARMACEUTICALS CORPORATION AND VEN-A-CARE OF THE FLORIDA KEYS, AND PROPOSED ORDER

Pursuant to 31 U.S.C. § 3730(b)(1), the United States hereby objects to the Settlement Agreement ("Agreement"), as presently drafted, between Schering-Plough Corporation ("Schering-Plough"), Schering Corporation ("Schering"), Warrick Pharmaceuticals Corporation ("Warrick") (collectively "Schering/Warrick") and Relator Ven–A-Care of the Florida Keys (the "Relator"). The United States also objects to the proposed Order Approving Settlement and Dismissal With Prejudice of Schering-Plough, Schering, and Warrick ("Proposed Order"). If approved, the Settlement Agreement would resolve *United States ex rel Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and, Warrick*

Pharmaceuticals Corporation, Civil Action No. 09-CV-10547 (the "Florida Civil Action") and *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Schering Corporation, Schering-Plough Corporation and Warrick Pharmaceuticals Corporation,* Civil Action No. 00-10698 (the "Massachusetts Civil Action").

The Relator initiated both the Florida and Massachusetts Civil Actions under Section 3730(b)(1) which provides that:

> A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

31 U.S.C. § 3730(b)(1). Because the Florida and Massachusetts Civil Actions were brought under Section 3730(b)(1), they may be dismissed *only if the Court and the Attorney General give written consent to the dismissal and their reasons for consenting*. For the reasons set forth below, the Government respectfully objects to the dismissal of the Florida and Massachusetts Civil Actions under the terms of the Settlement Agreement and Proposed Order as they are presently drafted.

SUMMARY OF SETTLEMENT AGREEMENT AND PROPOSED ORDER

Based on its review of the Agreement and Proposed Order, the Government understands the salient terms of the Agreement to be as follows. First, Schering/Warrick will pay $55 million dollars (the "Settlement Amount") into an escrow account. Agreement, Paragraph III(1). The Settlement Amount is to be divided among the State of California ("California"), the State of Florida ("Florida"), the Relator, the Relator's counsel, and the United States consistent with the Allocation Agreement to be filed with the Court. Id. at Paragraph III(2). Schering/Warrick was

not consulted about, and had no input into, the allocation of the Settlement Amount. Id.

Second, in exchange for some portion of the Settlement Amount, the Relator, on behalf of itself and the United States, will release Schering/Warrick for all claims it has or could have brought on behalf of the United States "arising out of or related to the Covered Conduct for the Covered Drugs . . . including but not be limited to the federal-share of any claim brought by a state arising out of or related to the Covered Conduct or Covered Drugs." Id. at Paragraph III(5). The "Covered Conduct" basically encompasses allegations that between January 1, 1991 through the Agreement's Effective Date, Schering and Warrick knowingly reported or caused to be reported false prices for the "Warrick Covered Drugs" and thereby caused false claims to be submitted to the Medicaid Program. Id. at Paragraph II(F). The "Covered Drugs" include both the "Warrick Covered Drugs" discussed in the Covered Conduct, and "Schering Covered Drugs," as reflected in Exhibit A to the Agreement. Notably, the Covered Drugs encompass not only drugs that were originally pled in both Civil Actions, but also numerous drugs that were not alleged in either Civil Action and that instead will be added to the Florida Civil Action as a condition of the Agreement. Agreement, Paragraph III(7). Attached as Exhibit 1 is a spreadsheet reflecting the drugs currently pled in the Civil Actions versus the Covered Drugs.

Third, the Settlement is conditioned upon the Court (a) resolving any "potential issues concerning the compliance of Schering with the liability standards set forth in the Court's June 21, 2007, decision in MDL No. 1456, (b) conducting an "independent review" of an analysis prepared by Schering of the Schering Covered Drugs as reflected in Exhibit A to the Agreement, and (c) "independently concurr[ing] that neither the WACs nor the AWPs for the [Schering Covered Drugs] constitute false statements within the meaning of the False Claims Act and that

claims for reimbursement based on such WACs and AWPs are neither deceptive nor unfair."

Agreement, Paragraph III(6). Among the findings of fact and rulings of law that the Court must enter as conditions to the Agreement are:

> [T]hat it has long been understood that, historically, the AWPs reported by the national drug pricing compendia (*i.e.,* FDB Bluebook, Redbook, and Medispan) for brand drugs typically represented an industry-wide, formulaic mark-up of 20% or 25% over the wholesale acquisition cost or WAC for that drug. Furthermore, the Court finds that it was widely understood in the industry, by the early 1990's, that some limited discounting off of WAC (typically, 2% to 5%) was generally available for brand drugs . . . .
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> [T]hat government payors, such as Medicaid, did not reasonably consider published AWPs that were generally within 30% of the average selling price for that drug (measured, conservatively, by Average Manufacturers Price or AMP calculated in accordance with all applicable HCFA/CMS regulations) to constitute a false or fraudulent statement, or to be misleading, deceptive, or unfair . . . .
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> [T]hat none of the WACS or AWPs for the Schering-brand drugs analyzed in Exhibit A to the Settlement Agreement constituted false or fraudulent statements, or were misleading, deceptive, or unfair . . . .
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> * * *
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> That the Relator has not sought to recover Medicaid proceeds for the Schering Covered Drugs where the AWP did not regularly exceed the average selling price by more than 30%; that the "yardstick" approach used by the Relator screened out brand drugs where the AWP was no more than 25% above a non-fictitious WAC and accepted as a "non-fictitious" a reported WAC that was no more than 5% above the drug's average selling price; and that this "approach to the settlement agreement of [the Florida Civil Action] under the False Claims Act to be reasonable and fair . . . .

Proposed Order, ¶¶ 2, 3, 5, 7.

ARGUMENT

At the outset, it is worth emphasizing that the United States does not object to the Parties reaching a settlement on these Civil Actions. The Government's objections are limited primarily to the scope of release as reflected in the Agreement and Proposed Order as they are presently drafted.

1. The Government objects to the Settlement Agreement and Proposed Order to the extent they state or suggest that the Relator may release or dismiss the United States's False Claims Act claims. See Agreement, Para. III(5)("[T]he Relator on behalf of the United States . . . fully and finally release, acquit and finally discharge . . . [Schering/Warrick."). While the Relator may release any claims *it* has or could have asserted on the United States's behalf to the extent that release binds only the Relator, it does not have the authority to actually release *the United States's* claims without the United States's express consent to do so. In other words, only the United States has the authority to release the claims of the United States against Schering/Warrick.

2. The Government objects to the Settlement Agreement and Proposed Order to the extent that they dismiss with prejudice the United States's claims against Schering/Warrick for the federal share of Medicaid damages arising from the Covered Conduct in states other than California and Florida. Although the Government was not privy to the Parties' settlement negotiations, it was provided with data, analyses, and proposed allocation agreement considered by Florida, California and the Relator to support the Settlement Amount. The Government was not provided any information to suggest that the Parties considered, or that the Settlement Amount included money allocable to resolve, the United States's claims for the federal share of

damages arising from Medicaid damages suffered in states other than California and Florida as a result of Schering/Warrick's alleged conduct.

Indeed, the Government declined to intervene against Schering/Warrick, in part, because it knew that several states had sued Schering/Warrick for the Covered Conduct and were presumably pursuing both the federal and state shares of their respective state's Medicaid damages. Here, where the Settlement Amount only pertains to damages suffered in California and Florida, the Agreement should not be allowed to release the United States's claims arising from the Covered Conduct in the other states.

3. The Government objects to the Settlement Agreement and Proposed Order to the extent they result in the dismissal with prejudice of the United States's claims against Schering/Warrick in connection with the Schering Covered Drugs and the Warrick Covered Drugs, except for the albuterol products. The relator never pled these drugs in the Civil Actions and the Government never investigated them (although Schering did provide the Government with its spread analysis on the Schering Covered Drugs (Exhibit A to the Agreement)). Under the qui tam provisions, if the relator intends to add claims beyond those initially pled, the United States has the right to investigate those allegations and make an intervention determination pursuant to the statute. 31 U.S.C. § 3730(b)(2). The relator should not be permitted to avoid the statutory scheme by including claims that have never been pled nor investigated by the United States, and as to which no intervention decision has been made.

Moreover, in the context of this Settlement, the Government will not receive any consideration for the Schering Covered Drugs, or for the Warrick Covered Drugs (except for Medicaid damages suffered in California and Florida). It is for precisely this type of problem

that Congress made the release of the United States's claims conditional upon the approval of the Attorney General. 31 U.S.C. § 3730(b)(1). If the Settlement Agreement and Proposed Order are approved as presently drafted, the United States would be in a worse position than if no qui tam action had been brought at all, at least with regard to the Schering Covered Drugs and some of the Warrick Covered Drugs. The United States should not be required to forego its right to pursue possible actions merely because a relator has brought a qui tam action and then agreed to dismiss it without providing any benefit for the United States.

4. The Government objects to the Parties conditioning the Settlement Agreement upon the Court effectively issuing an advisory opinion on the Schering Covered Drugs. Federal Courts have limited jurisdiction and must resolve actual cases and controversies. *See Overseas Military Sales Corp. V. Giralt-Armada*, 503 F.3d 12, 16 (1st Cir. 2007); *Osediacz v. City of Cranston*, 414 F.3d 136, 139 (1st Cir. 2005). The Constitution's case or controversy requirement prevents federal courts from issuing advisory opinions and "limit[s] the business of federal courts to questions presented in an adversary context." *Giralt-Armada*, 503 F.3d at 17 (quoting *Flast v. Cohen*, 392 U.S. 83 (1968)).

Here, there is no case or controversy in connection with the Schering Covered Drugs. As noted above, the Schering Covered Drugs are not presently pled in either the Florida or Massachusetts Civil Actions. Moreover, if and when the Relator amends the Florida Civil Action to encompass the Schering Covered Drugs– nearly 15 years after the Relator filed the Florida Civil Action– both the Agreement and Proposed Order make it crystal clear that the Relator does not believe and will not allege that the reported WACs and AWPs for the Schering Covered Drugs give rise to False Claims Act liability. In the absence of an actual, or even an

apparent, dispute between the Relator and Schering/Warrick, a judicial ruling on the Schering Covered Drugs is nothing more than an advisory opinion.

The most plausible explanation for why Schering/Warrick seeks such a ruling from the Court is so that Schering/Warrick may use the ruling to influence the outcome of other pending AWP litigation against it, to which neither the Relator nor the United States is a party. It is telling that the Schering/Warrick supports the appropriateness of the Settlement by focusing solely on the Schering Covered Drugs, and fails to even mention the Settlement Amount or whether the federal share of that Settlement Amount is commensurate to the scope of the claims purportedly being released. Under these circumstances the Court should not permit Schering/Warrick to use the settlement of the Florida and Massachusetts Civil Actions to further a litigation objective in other pending cases. Whether the reported prices for the Schering Covered Drugs would support claims under the False Claims Act, or under any other state law, should be resolved in a real case or controversy; not in the present context where the truth-seeking function of the adversary process is absent.

5. Should the Court decide to proceed with independently evaluating the Schering Covered Drugs, the Government objects to the proposed findings of fact and rulings of law for various reasons. First, there is an insufficient evidentiary record before the Court to render any ruling as to the truth or falsity of the prices Schering reported for its branded products. The only "evidence" before the Court is a presentation generated by Schering's counsel. The Court does not have the reported WACs, AWPs, ASPs, or AMPs for the Schering Covered Drugs. The Court does not have any information on how Schering calculated those reported prices and whether they accurately reflected all relevant discounts, rebates and chargebacks. Regarding all

the "Sales at List [prices]," there is no evidence concerning what percentage of those customers received chargebacks or discounts that may have affected the ultimate effective prices. In the absence of such evidence, it would be difficult to make factual findings regarding what the reported prices actually represent, much less whether they were false, fraudulent, misleading, deceptive, or unfair.

Likewise, the Government objects to all the proposed findings of fact regarding the federal payors. The Government does not dispute the Court's extensive knowledge regarding AWP-related matters. Nevertheless, the Parties have not provided an evidentiary basis for the Court to make a factual finding on whether a government payor, such as Medicaid, knew when a published AWP was within 30% of the average selling price or the average manufacturer price, much less considered whether such an AWP is false, fraudulent, misleading, deceptive, or unfair, as suggested in Proposed Order, Para. 3. As the Court is well aware, an extensive amount of discovery has been taken in connection with the three *qui tam* actions in which the United States has intervened. Any findings of fact regarding the government's knowledge or considerations should be made in the context of a fully developed factual record.

CONCLUSION

For the reasons stated above, the United States respectfully objects to the Settlement Agreement and Proposed Order as presently drafted. The United States is willing to work with the Parties to draft an acceptable Agreement and Proposed Order.

Respectfully submitted,

For the United States of America,

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CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "Objection to the Settlement Agreement Between Schering-Plough Corporation, Schering Corporation, Warrick Pharmceuticals Corporation and Ven-A-Care of the Florida Keys and the Proposed Order" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Andy J. Mao
Andy J. Mao

Dated: July 21, 2009

Exhibit 1: Comparison of the Drugs Pled in Florida and Massachusetts Civil Actions and those released as part of the Settlement Agreement and Proposed Order

Florida Civil Action Drugs (Fourth Amended Complaint)	Massachusetts Civil Action Drugs (Third Amended Complaint)	"Warrick Covered Drugs" (Exhibit E to Settlement Agreement)	"Schering Covered Drugs" (Exhibit F to Settlement Agreement)
Albuterol Sulfate solution	Albuterol Inhalation Aerosol	Albuterol Sulfate/Albuterol	n/a
		Amoxicillin	Cedax
		Betamethasone	Celestone Soluspan
		Captopril	Clarinex
		Cholestryamine	Claritin
		Cimetidine	Claritin D
		Clotrimazole	Diprolene
		Cromolyn Sodium	Elocon
		Flurbiprofen	Eulexin
		Glyburide	Foradil
		Griseofulvin	IMDUR
		ISMN	IMDUR Tablet
		Labetalol HCL	Intron A
		Mexiletine	K-Dur
		Mometasone Furoate	Lotrimin
		Oxaprozin	Lotrisone

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		Perphenazine	Nasonex
		Potassium Chloride	Nitro-Dur
		Ribavirin	Normodyne
		Selegiline	Peg-Intron
		Sodium Chloride	Proventil
		Sulcrafate Tablets	Rebetol
		Theophylline	Rebetron
			Sebizon
			Solganal
			Temodar
			Theo-Dur
			Trinalin
			Vancenase
			Vanceril